UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

UNITED STATES, *ex rel.* BAHNSEN, *et al.*,	:	
Plaintiffs,	:	
vs.	:	Case No.: 11-cv-1210 (SDW) (MCA)
BOSTON SCIENTIFIC NEUROMODULATION CORPORATION,	:	
Defendant.	:	

DEFENDANT'S MEMORANDUM OF LAW IN SUPPORT OF MOTION TO DISMISS

Felice B. Galant
Fulbright & Jaworski L.L.P.
666 Fifth Avenue
New York, New York 10103
Telephone: 212-318-3000
Telecopier: 212-318-3400
fgalant@fulbright.com

Frederick Robinson
(admitted *pro hac vice*)
Lesley C. Reynolds
(admitted *pro hac vice*)
Fulbright & Jaworski L.L.P.
801 Pennsylvania Avenue, NW
Washington, DC 20004
Telephone: 202-662-0200
frobinson@fulbright.com
lreynolds@fulbright.com

Attorneys for Defendant

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Defendant Boston Scientific Neuromodulation Corporation ("BSNC" or "Defendant") hereby brings this Motion to Dismiss Relators' Amended Complaint pursuant to Federal Rules of Civil Procedure 12(b)(6), 8(a) and 9(b). Relators have failed to state a claim upon which relief can be granted, and Relators have failed to allege their claims with the requisite particularity required under the Federal Rules. Simultaneously with this Motion to Dismiss, Defendant has submitted a Motion to Strike Confidential and Protected Health Information from the Relators' First Amended Complaint. Defendant urges the Court to review the Motion to Strike first, or alternatively to review both the Motion to Strike and this Motion to Dismiss together, so that the "final" version of the First Amended Complaint is what the Court considers when deciding this Motion to Dismiss.

I. BACKGROUND[1]

BSNC manufactures, sells, and supplies the spinal cord stimulation ("SCS") system known as the Precision Plus™ SCS System. (Am. Compl. ¶¶ 16-17). The Precision Plus™ SCS System consists of both an implanted device and external accessories. The implanted device sends electrical signals through leads that are

[1] For purposes of this motion to dismiss only, the Relators' factual allegations are accepted as true.

inserted along a patient's spinal cord under the skin, and is used to treat chronic pain of the trunk and limbs. (*Id.* ¶¶ 17, 90.) The system's external accessories include a wireless remote control, a cordless battery charger, and the Precision Adhesive Kit. (*Id.* ¶ 17.)

BSNC employed Relator Wendy Bahnsen in BSNC's Customer Service Department, where she assisted patients with issues they were having with the Precision Plus™ SCS System, from March 2008 through January 2009. (*Id.* ¶ 8.) In January 2009, Relator Bahnsen was transferred to BSNC's Billing and Collections Department where she worked until her termination on October 15, 2009. (*Id.* ¶¶ 7-8.) Relator Carolina Fuentes worked as an assistant to BSNC's Vice President of Health Economics and Reimbursement before being transferred to BSNC's Billing and Collections Department in February 2009. (*Id.* ¶ 13.) Relator Fuentes then worked in the Billing and Collections Department until June 2010. (*Id.*) According to their First Amended Complaint, as a member of the Billing and Claims Department, beginning in early 2009, Relator Bahnsen submitted claims on behalf of BSNC to insurers in order to obtain reimbursement for products associated with the Precision Plus™ SCS System. (*Id.* ¶ 9.)

On March 2, 2011, Relators Bahnsen and Fuentes (collectively herein "Relators") filed a *qui tam* complaint under seal against BSNC, alleging violations

of the federal False Claims Act ("FCA"), 31 U.S.C. § 3729 *et seq.*, as well as the laws of 27 states and the District of Columbia, in connection with claims submitted to the Government for the Precision Plus™ SCS System and its accompanying accessories. After investigating for more than a year, on February 24, 2012, the federal government declined to intervene in the case (Dkt. 8), and the case was unsealed on February 28, 2012. (Dkt. 9.) The 27 states and the District of Columbia declined to intervene on April 23, 2012. (Dkt. 12.) The case was dismissed against BSNC with respect to Maryland state law with prejudice on May 7, 2012. (Dkt. 13.)

On September 10, 2012, Relators filed their First Amended Complaint, again alleging that BSNC violated the FCA by engaging in improper billing schemes that resulted in the submission of false claims to the Government. (*See* Am. Compl. ¶¶ 23-54.) Additionally, Relators now claimed that BSNC failed to report adverse events related to the Precision Plus™ SCS System and charged the Government for defective equipment, which caused the Government to reimburse BSNC for claims that were not "reasonable and necessary." (*Id.* ¶¶ 85-87.) Relators further contended that Defendant promoted the Precision Plus™ SCS System for off-label purposes and provided physicians with free reimbursement services in order to encourage physicians to order the Precision Plus™ SCS System. (*Id.* ¶ 106.)

Relators also re-asserted their state law claims against 25 states and the District of Columbia. (*Id.* ¶¶ 175-357.) Finally, Relators alleged, as they did in their Original Complaint, that BSNC improperly retaliated against them by terminating their employment relationships when Relator Bahnsen complained about BSNC's billing practices. (*Id.* ¶ 143.)

II. LEGAL STANDARD

To survive a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6), a complaint must plead "enough facts to state a claim to relief that is plausible on its face." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007). "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). The pleadings must establish claims that cross "the line from conceivable to plausible." *Twombly*, 550 U.S. at 570. A complaint alleging facts that are "merely consistent with a defendant's liability . . . stops short of the line between possibility and plausibility of entitlement to relief." *Iqbal*, 556 U.S. at 678 (*quoting Twombly*, 550 U.S. at 557).

To withstand a motion to dismiss a "complaint must set forth sufficient information to suggest that there is some recognized legal theory upon which relief may be granted." *Eli Lilly & Co. v. Roussel Corp.*, 23 F Supp. 2d 460, 475 (D.N.J.

Jul. 7, 1998). Although a court must accept as true "well-pleaded" factual allegations made in the complaint, a court need not credit a complaint's 'bald assertion' or 'legal conclusions.'" *Morse v. Lower Merion Sch. Dist.*, 132 F.3d 902, 906 (3d Cir. 1997).

Because FCA actions are actions based in fraud, the heightened pleading requirements of Federal Rule of Civil Procedure 9(b) also apply. *See Mason v. Coca-Cola Co.*, 774 F. Supp. 2d 699, 702 (D.N.J. 2011). In alleging fraud, "a plaintiff must allege the 'who, what, when, where, and how' of the claim." *See id*. "The rule's heightened pleading requirements 'give [defendants] notice of the claims against them, provides an increased measure of protection for their reputations, and reduces the number of frivolous suits brought solely to extract settlements.'" *See id*. For the reasons stated below, Relators have failed to meet these standards. Consequently, Relators' Complaint should be dismissed.

III. RELATORS HAVE FAILED TO STATE A CLAIM UPON WHICH RELIEF CAN BE GRANTED AS TO THEIR BILLING ALLEGATIONS

Relators first attack BSNC's billing practices related to the external accessories for the Precision Plus™ SCS System. (*See* Am. Compl. ¶ 23.) Relators specifically allege that BSNC: (1) submitted claims for the external accessories without a physician's order of medical necessity; (2) changed or made

up diagnosis codes for the external accessories that were submitted on Government claim forms; and (3) falsely certified compliance with the law on Government claim forms. (*Id.*) Notably, Relators do not contend – nor could they – that Defendant submitted any claims to the Government for payment related to the implantation of the SCS device.[2]

The Relators' false billing allegations fail as a matter of law, because Medicare rules and guidance contradict the Relators' allegations. The Centers for Medicare & Medicaid Services ("CMS") has created the CMS Manual System, which contains policies, procedures, and instructions for the provision of services and billing for such services under Government programs. The CMS Manual System contains interpretive rules that are binding upon Medicare providers and suppliers. *See In re Cardiac Devices Qui Tam Litig.*, 221 F.R.D. 318, 351-353 (D. Conn. 2004) ("[T]o adopt defendant's position that interpretive rules are not

[2] Hospitals and physicians submit claims for payment for the implantation of the prosthetic device itself. *See e.g.* Medicare Claims Processing Manual, Pub. 100-04, Ch. 14 § 10.2 ("[Ambulatory surgical center ("ASC")] services for which payment is included in the ASC payment for a covered surgical procedure under 42 C.F.R. § 416.65 include, but are not limited to . . . Implanted prosthetic devices, including intraocular lenses (IOLs), and related accessories and supplies not on pass-through status . . . ."); *See also United States ex rel. Bennett v. Boston Sci. Corp*, No. H-07-2467 2011 U.S. Dist. LEXIS 34745, at * 78 (S.D. Tex 2011) (discussing same in a medical device context). Relators have not alleged that the claims submitted for the System implantations suffered from the same deficiencies as the claims for the accessories.

binding would effectively nullify the Medicare manuals in their entirety[.]"). Contractors, providers, and suppliers are required to consult this Manual System to answer questions regarding coverage eligibility and claims processing. *See id.* at 351-352 (citations omitted) (stating that failing to follow the guidance provided in Medicare manuals has resulted in numerous cases imposing liability under the False Claims Act). Because Relators have ignored relevant guidance from CMS, which demonstrates that BSNC's actions did not result in the submission of false claims, Relators have not stated a claim upon which relief can be granted.

A. Relators' claims regarding physicians' orders ignore Medicare guidelines.

Applicable Medicare guidance refutes Relators' allegations that BSNC engaged in improper billing practices by submitting claims for external accessories to the Precision Plus™ SCS System without first receiving physicians' orders. The Medicare National Coverage Determinations Manual, Publication 100-03, specifies the coverage criteria for Electrical Nerve Stimulators, such as the Precision Plus™ SCS System. *See* Medicare National Coverage Determinations Manual, Pub 100-03, Pt. 2 § 160.7. The Government will provide reimbursement for stimulators

under the prosthetic device benefit.[3] *Id.* Medicare covers these devices when they are furnished pursuant to a physician's order. *Id.* Coverage for prosthetic devices automatically includes coverage for supplies, replacement, and repairs to the prosthetic device, and CMS Manuals do not state that a separate physician's order is required to prove the medical necessity of supplies for a prosthetic device. Medicare Benefit Policy Manual, Pub. 100-02, Ch. 15 §§ 120(D), 110.2. If patients require replacement supplies in order to efficiently operate a piece of durable medical equipment or a prosthetic device, a physician may specify on the initial order the types of supplies necessary and the frequency with which the patient may obtain the supplies. Medicare Program Integrity Manual, Pub. 100-08, Ch. 5 § 5.9. In this case, the physician's initial order for the implanted device would serve as "medical evidence for supply replacement claims." *Id.* A new physician's order is only required if an item is replaced or there is a change in the order for the supply or accessory. *Id.* at § 5.2.4.

In their First Amended Complaint, Relators initially claim that BSNC improperly billed the Government for the external accessories to the Precision

[3] CMS manuals define "prosthetic devices" as those devices that "replace all or part of an internal body organ . . . or replace all or part of the function of a permanently inoperative or malfunctioning internal body organ[.]" Medicare Benefit Policy Manual 100-02, Ch. 15 § 120. Medicare covers durable medical equipment, prosthetics, orthotics, and supplies ("DMEPOS") under Medicare Part B. *See* 42 U.S.C. § 1395m(a).

Plus™ SCS System because BSNC had not obtained separate physicians' orders for the external accessories (*see* Am. Compl. ¶¶ 40-41), distinct from the physicians' orders for the implant itself. Relators also claim that BSNC shipped the external accessories to patients prior to receiving physicians' orders. (*Id.* ¶ 40.) Based on the guidance in the CMS Manual System, however, Relators' allegations that Defendant fraudulently submitted claims without appropriate documentation simply cannot stand. As a nerve stimulator, the Precision Plus™ SCS System would be reimbursed under the prosthetic device benefit when furnished pursuant to a physician's order. *See* Medicare National Coverage Determinations Manual, Pub. 100-03, Pt. 2 § 160.7. In addition, all of the accompanying external accessories, including the wireless remote control, the cordless battery charger, and the Precision Adhesive Kit, would be automatically covered pursuant to the same physician's order. Medicare Benefit Policy Manual, Pub. 100-02, Ch. 15 §§ 120(D), 110.2. Therefore, because the initial physician's order for the Precision Plus™ SCS System by itself would support the medical necessity of the implanted device, its external accessories, and replacement of those external accessories, Relators have not adequately alleged that BSNC submitted false claims to the government for the external accessories. Allegations of billing actions that are merely consistent with a theory of liability, rather than leading one to believe there

is plausible liability, do not satisfy the pleading requirements of Rule 8(a). *See Iqbal*, 556 U.S. at 678. Relators' allegations that BSNC shipped external accessories prior to the receipt of physicians' orders instead betray Relators' failure to realize that CMS guidance *permits* BSNC to ship external accessories pursuant to the ***initial*** physician's order or a ***previous*** physician's order for the implanted device. As a result, Relators have not alleged the submission of any ***false*** claim, due to the purported lack of separate physicians' orders for the external accessories. Without any predicate false claim, this portion of the Amended Complaint fails as a matter of law.

B. Relators cannot allege that Defendant's reporting of diagnosis codes was improper or material to any claim for payment.

Relators allege that BSNC submitted false claims to the government by changing and making up diagnosis codes on claims for the external accessories in violation of Medicare rules and OIG guidance. (*See* Am. Compl. ¶¶ 32-39.) Relators further claim that BSNC used the general diagnosis code 724.2 (Lumbago-back pain) when it submitted claims for the external accessories for the Precision Plus™ SCS System because it was "financially advantageous" for BSNC to use such codes. (*Id.* at ¶ 33.) However, Relators ignore that it is appropriate in certain instances for a supplier to provide diagnosis codes.

The Medicare Claims Processing Manual explains that valid diagnosis codes are required for all electronically submitted DMEPOS claims. *See* Medicare Claims Processing Manual, Pub. 100-04, Ch. 23 § 10. However, if physicians provide only a narrative description of the diagnosis, rather than the specific diagnosis code, suppliers "may choose to utilize a variety of sources to determine the most specific diagnosis code to include on the individual line item of the claim." *Id.* In determining the specific diagnosis code, suppliers may look to coding resources, documentation in the patient's medical record, and other contact with health professionals, among other avenues. *Id.* Thus, the Medicare guidance specifically allows suppliers to engage in the process that Relators complain of in this matter.

Moreover, Relators are also mistaken that the diagnosis code is material to the approval of the claim or to the amount of payment on a claim for the external accessories. The Third Circuit has held that there is a materiality component to the FCA, and this standard has been written into the more recent revisions of the FCA. "The FCA defines 'material' as having a 'natural tendency to influence, or be capable of influencing, the payment or receipt of money or property.'" *United States ex rel. Wilkins v. United Health Group, Inc.*, 659 F.3d 295, 303 (3d Cir.

2011) (*citing* 31 U.S.C. § 3729(b)(4). Here, there are two reasons why Relators cannot show materiality.

First, payment for prosthetic devices is determined by the Health Common Procedure Coding System ("HCPCS") fee schedule for the item, less any deductible. *Id.* at § 1395m(a); 42 C.F.R. § 414.210(a). For items included in the HCPCS fee schedule, the Social Security Act requires suppliers to use fee schedules under Medicare Part B in order to receive reimbursement for DMEPOS. *See id.* at § 1834(a); Medicare Claims Processing Manual, Pub. 100-04, Ch. 20 § 20. DMEPOS items are divided into different Medicare payment categories, and each category has its own reimbursement rules. *See* 42 U.S.C. § 1395m. Reimbursement amounts for supplies listed in the HCPCS fee schedule do not vary based on the diagnosis code provided on the claim for the device. As a result, there could be no "financial advantage" to BSNC from supplying one code versus another. Because the external supplies for an implanted system will already be reimbursable on the basis of the diagnosis code that supported the original implantation, any error in the diagnosis code supplied with a claim for external accessories will not be material to Medicare's payment decision. Given this lack of materiality, Relators' claims relating to diagnosis codes fail to state a claim as a matter of law.

Second, the diagnosis code provided on a claim for the external supplies is simply not material to Medicare's payment decision, because the diagnosis code that was submitted to Medicare to support the initial claim for the implanted device will also supply any subsequent claim for the external accessories. *See* Medicare Benefit Policy Manual, Pub. 100-02, Ch. 15 §§ 120(D), 110.2.

C. Because Relators have not shown any diagnosis code provided was inaccurate, Relators cannot proceed under a theory of false certification.

In their Amended Complaint, Relators allege that BSNC's fraudulent billing practices resulted in numerous legally false certifications to the Government. (*See* Am. Compl. ¶¶ 46-47, 126, 128.) A claim is legally false under the FCA when a claimant knowingly certifies to the Government that it has complied with certain statutes or regulations, and such compliance is a condition for Government payment of the claim. *See Wilkins*, 659 F.3d at 305. Legally false claims may be express or implied. *Id.* An entity is liable for making a legally express false claim by explicitly certifying to the government that it complied with statutes and regulations that are preconditions to payment by the Government for the claim. *Id.* The Third Circuit has also recognized false claims liability for legally implied false claims. *Id.* at 306. Implied false certification liability under the False Claims Act occurs if a claimant makes a claim for Government payment without specifically

certifying that it violated statutes or regulations that are required in order to receive payment. *Id.* at 305.

In this case, Relators claim that BSNC submitted legally express false certifications to the Government by allegedly falsifying CMS-1500 forms. (*See* Am. Compl. ¶¶ 46-47, 116-117, 126, 128.) Specifically, Relators claim that BSNC violated the FCA by: (1) certifying that the external accessories were medically necessary without having knowledge of that fact; and (2) certifying that the information contained on the forms was true and complete. (*Id.* at ¶¶ 46- 47, 126, 128.) For the reasons set forth below, Relators have not alleged a falsity arising out of any claims submitted by BSNC that would give rise to liability under a false certification theory.

Under the FCA, claims are factually false if the claimant misrepresents to the Government the goods or services it provided to individuals. *See Wilkins*, 659 F.3d at 305. Relators also allege that BSNC submitted factually false claims to the Government by either using different diagnosis codes on the CMS-1500 claim forms than the code provided by the physician or inserting its own diagnosis code if the physician did not provide one. (*See* Am. Compl. ¶¶ 38, 42-43, 45.) However, as noted above, the Medicare Manuals clearly allow suppliers to insert a diagnosis code if one is not specifically provided and a narrative description of the

patient's condition is provided instead. In addition, the medical necessity of the external supplies was already established by the medical necessity of the implantable device.

Moreover, to the extent that the protected health information ("PHI") that Relators improperly included in their First Amended Complaint is not stricken, the tables in Relators' First Amended Complaint clearly include clams that could be proper.[4] While Defendant is reluctant to even discuss the PHI included in the tables, a brief review shows that for the majority of claims in Relators' improperly included tables, the diagnosis codes submitted on the CMS-1500 claim form could have been submitted correctly. For example, in paragraph 34, Relators claim that even though Dr. BV[5] did not provide a diagnosis code on a physician's order, BSNC inserted diagnosis code 724.2 on the corresponding CMS-1500 form. (*See* Am. Compl. ¶ 34.) However, in this and every other instance in Table 1 where Relators claim that a physician did not include a diagnosis code on an order,

[4] In the event that the Defendant's Motion to Strike is denied, Defendant concedes that Relators have plead their billing allegations with enough detail to survive Federal Rule of Civil Procedure 9(b). However, the Relators' allegations still fail as they have not stated a claim upon which relief can be granted under Federal Rule of Civil Procedure 12(b)(6). In the event the tables are stricken from the record as they should be, Relators have also not alleged adequate detail as to their billing allegations under Federal Rule Civil Rule of Procedure 9(b).

[5] Physician names have been de-identified herein to stop the flow of improperly referenced HIPAA-protected data.

Relators have failed to allege that the physician did not provide a narrative description for the diagnosis code or that BSNC did not have any access to other information that supported its code selection.

Relators set forth additional and similarly flawed examples, such as the claim submitted by Dr. SH for an Adhesive Kit, which included the diagnosis code 724.4 on the physician's order. According to Relators, BSNC submitted the CMS-1500 form for this clam with the codes 724.4 and 722.83. (*See id.)* However, nothing in the Medicare Manuals prohibits a supplier from adding a more specific diagnosis code to a claim form.

Consequently, BSNC did not provide or submit any ***false*** information or claims to the Government, because BSNC followed relevant Medicare rules and guidelines in the submission of claims relating to the external accessories to the Precision Plus™ SCS System. Even assuming, *arguendo*, that BSNC had inserted or changed diagnosis codes as Relators have alleged, Relators have failed to recognize that the Precision Plus™ SCS System cannot operate without the external accessories, which includes the wireless remote control, cordless battery charger, and the Precision Adhesive Kit. If patients have already received the implant pursuant to a particular diagnosis code, including 724.2, it is simply unfathomable that a ***different*** diagnosis code would apply to the external

accessories. Furthermore, without the external accessories, the implant itself would be worthless, and patients requiring the use of the Precision Plus™ SCS System would be unable to receive the necessary supplies to treat their chronic pain.

Just as importantly, what Relators have set forth in their First Amended Complaint actually describes acceptable billing practices for suppliers of prosthetic devices. Relators have overlooked relevant CMS guidance regarding the submission of claims for the external accessories. At most, Relators have alleged that it is conceivable that an error could have been made in the selection of diagnostic codes by BSNC; however, conceivability does not create liability under the FCA. Therefore, without the submission or certification of ***false*** claims on CMS-1500 forms, Relators' claims fail as a matter of law, as these claims do not raise to the level of factually or legally false certifications.

IV. RELATORS' IMPROPER BILLING ALLEGATIONS REGARDING THE FAILURE TO REPLACE DEFECTIVE EQUIPMENT UNDER WARRANTY ARE INSUFFICIENT.

Relators also allege that BSNC improperly billed the Government for replacement devices and equipment that BSNC allegedly should have covered under warranties. (*See* Am. Compl. ¶ 87.) However, Relators provide so little data

as to these claims that it is impossible to tell if Government Programs were even billed.

Although Relators provide a single example where BSNC allegedly denied a customer a free replacement of the Precision Charger 2.0 product (*see id*. at ¶ 70-71), Relators concede that they have no actual knowledge of a false claim being submitted for payment to a Government program for the product. (*See id.* at ¶ 72) (speculating only that the patient's insurance carrier was "most likely Medicare"). For this reason alone, the Relators' claims should be dismissed under Rule 9(b). Moreover, even assuming Relators could allege these patients were covered under Medicare, nothing prohibits Medicare from reimbursing a supplier for a device or accessories for a device that are no longer covered under a warranty. *See* Medicare Benefit Policy Manual, Pub. 100-02, Ch. 16 § 40.4. Relators' other warranty claims fail for similar reasons. (*See e.g.* Am. Compl. ¶ 71) (referencing once again only that a patient was referred to his or her generic "insurance company" when the product was not covered by warranty.) This Court cannot, and should not be required to, read Relators' mind and determine the details of this specific claim for basic details such as whether government programs are implicated. Such hypothetical presumptions are the exact pleading deficiencies that *Iqbal* rejects. *See Iqbal*, 556 U.S. at 678. Rather, Relators must plead their false claims

allegations with sufficient particularity, as required by Federal Rule of Civil Procedure 9(b), and consequently Relators' warranty claims must be dismissed.

V. RELATORS HAVE FAILED TO PLEAD THEIR ADVERSE EVENT REPORTING CLAIMS WITH PARTICULARITY

The Federal Food and Drug and Cosmetic Act ("FDCA") requires medical device manufacturers to report adverse event incidents. *See* 21 U.S.C. § 360i(1). Relators contend that BSNC knew that customers had encountered problems as a result of "defective equipment" that accompanied the Precision Plus™ SCS System. (Am. Compl. ¶ 74.) Relators claim that BSNC was required to report these incidents to the FDA as adverse events, and that BSNC knew that these product defects rendered these products "not reasonable and necessary." (*Id*. ¶ 85.) Relators argue that, as a result of continuing to supply these products, BSNC knowingly caused false claims to be submitted to government programs. (*Id.* ¶ 87.) Relators do not, however, allege a single false claim that was actually submitted to a government program as a result of BSNC's failure to report adverse events. Relators' pleadings therefore cannot satisfy Rule 9(b).

Courts routinely reject FCA cases premised on a purported failure to file adverse event reports with the FDA. The United States District Court for the District of Massachusetts has had several recent cases arising out of adverse event

reporting, and has consistently found that these claims do not give rise to liability under the FCA.

In the case of *United States ex rel. Provuncher v. Angioscore, Inc.*, No. 09-12176-RGS, 2012 U.S. Dist. LEXIS 60390, at *13 (D. Mass. May 1, 2012) [hereinafter *Provuncher I*], the relator argued that the EX Catheter product routinely separated, and this defect rendered the product defective. Similar to the case at bar, the relator in *Provuncher I* alleged that the manufacturer violated the FCA by concealing adverse event information from the FDA relating to alleged defects in the catheter and claimed such information would have been material to the government's decision to pay claims for the device. *Id.* at *5-6. The court disagreed and dismissed the case under Federal Rule of Civil Procedure 9(b), because the Relator failed to show that the defendant had presented a false claim to the government. *Id.* at *12. The Relators were given leave to amend and again in an amended complaint argued that any claim for payment of the defective EX Catheter was *ipso facto* a false claim under the FCA, because every catheter that was sold was defective and thus had no value. *United States ex rel. Provuncher v. Angioscore, Inc.*, No. 09-12176-RGS, 2012 U.S. Dist. LEXIS 108487, at *4 (D. Mass. Aug. 3, 2012) (dismissing second amended compliant) [hereinafter *Provuncher II*]. The Court again dismissed the relator's complaint recognizing that

"the provision of a sophisticated medical device that almost inevitably will be subject to a statistically predictable failure rate, is not the evil that Congress sought to root out by passage of the False Claims Act." *See id.* at *4.

The Eighth Circuit similarly found that allegations of consumer injury and non-compliance with FDA regulations were "arguably relevant to a products liability case but . . . [were] insufficient to satisfy the Rule 9(b) requirement that the FCA fraud claims be pleaded with particularity." *See United States ex rel. Roop v. Hypoguard USA, Inc.* 559 F.3d 818, 822-823 (8th Cir. 2009) (affirming the district court's dismissal of the relator's first amended complaint where relator alleged that diabetes-related medical devices and accessories were defective, and that such defects were not properly reported, but failed to identify false or fraudulent reimbursement claims or allege how "any product defect . . . was material to . . . the government's decision to pay . . . unidentified Medicare reimbursement claims").

Similarly here, Relators' allegations about adverse event reporting fail to plead a violation of the FCA. At no time do Relators tell us what false claims were submitted as a result of the alleged failure to report adverse events. Nor do they explain how the failure to make these reports was material to any payment

decision. Consequently, their claims arising out of adverse event reporting must be dismissed.

VI. RELATORS' ADVERSE EVENT CLAIMS ARE ALSO BARRED UNDER THE PUBLIC DISCLOSURE DOCTRINE

Even assuming *arguendo*, that Relators were able to allege a cognizable claim under the FCA based on BSNC's purported to disclose adverse events to the FDA, their claims would still be barred under the public disclosure bar of the FCA. The public disclosure bar provides that a court "shall dismiss an action or claim under this section, unless opposed by the Government, if substantially the same allegations or transactions as alleged in the action or claim were publicly disclosed . . . unless the action is brought by the Attorney General or the person bringing the action is an original source of the information." 31 U.S.C. § 3730(e)(4). In order to qualify as a public disclosure, the disclosure must have taken place either "(i) in a Federal criminal, civil, or administrative hearing in which the Government or its agent is a party; (ii) in a congressional, Government Accountability Office, or other Federal report, hearing, audit, or investigation; or (iii) from the news media . . ." *See id.*

A. The adverse event reporting issues of which Relators complain have already been publicly disclosed, in any investigation.

Relators allege that BSNC's failure to characterize adverse event reports correctly with respect to the Precision Plus™ SCS system led to an underreporting

of errors that ultimately resulted in an FDA violation. However, the exact nature of the adverse event reporting issues was already the subject of a federal report and investigation. BSNC participated in a lengthy remediation of several issues with the Food and Drug Administration beginning in 2009. One of the issues that was reported on at length during the time period of April 2009 – October 2010 was the potential underreporting of the adverse event reports related to the Precision Plus™ System. *See* Decl. of Felice Galant, Exhibit 1.[6] As a result of discussions between BSNC and the FDA, BSNC filed an additional 500 adverse event reports with the agency. These letters to the FDA specifically addressed whether BSC should report as adverse events certain incidents that had not previously been classified as complaints. The letters and subsequently filed adverse events reports were requested by the FDA pursuant to its regulatory authority and would have clearly put the government on notice of any fraudulent activity, relating to an under-reporting of adverse events. *Graham County Soil & Water Conservation Dist. v. United States ex rel. Wilson*, 130 S. Ct. 1396, 1410 (2010) (stating that "the statutory touchstone . . . is whether the allegations of fraud have been 'public[ly] disclos[ed], not whether they have landed on the desk of a DOJ lawyer"')

[6] Information related to products not at issue in this lawsuit has been redacted. In the event that an appropriate protective order is put in place, Defendant will provide unredacted copies to opposing counsel.

(alterations in original) (citations omitted). Moreover, the FDA Adverse Event Reporting System ("FAERS") database, which contains information regarding adverse events that companies have submitted to the FDA, is available to the public.[7] These communications between BSNC and the FDA consequently qualify as a public disclosure that would trigger the FCA's jurisdictional bar.

B. Relators are not original sources of the information.

Because the multiple communications between BSNC and the FDA, including any late-filed adverse event reports, satisfy the public disclosure requirement, Relators are only entitled to bring this action if they qualify as original sources. An original source is defined as an individual who "either (i) prior to a public disclosure under subsection (e)(4)(a), has voluntarily disclosed to the Government the information on which allegations or transactions in a claim are based, or (ii) who has knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions, and who has voluntarily provided the information to the Government before filing an action under this section." *See* 31 U.S.C. § 3730. Relators cannot meet these original source requirements.

[7] *See FAERS (formerly AERS)*, Sept. 10, 2012, http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/default.htm (stating that FAERS data is available to the public through FAERS statistics, FAERS data files, or filing a Freedom of Information request to the FDA.)

First, Relators cannot qualify under the first prong of this test, as they do not allege that they provided their information to the government before the public disclosures at issue, which occurred over a period of several months beginning in April 2009. Relators do not even claim to have produced the publicly disclosed information to the government prior to its disclosure, by BSNC to the FDA. Instead, Relators' plead that they only provided "non-public information to the government prior to filing this action." (Am. Compl. ¶¶ 12, 15.) Relators first filed their lawsuit in March of 2011 (Dkt.1), almost two years after the remediation efforts were well-documented with the FDA. *See* Decl. of Felice Galant, Ex. 1. Accordingly, Relators have not satisfied the first requirement of the original source test.

Second, Relators do not satisfy the next prong of the original source criteria, as they have no knowledge of these claims that materially add to the public disclosure. *See* 31 U.S.C. § 3730(e)(4)(a). The lack of detail and specificity that plagues these claims under Rule 9(b) also prevents Relators from meeting this original source knowledge standard, as they simply have not plead any specific false claims. As such, Relators' claims relating to adverse event reports should be dismissed under the public disclosure bar.

VII. RELATORS' OFF-LABEL ALLEGATIONS CANNOT SUPPORT A CLAIM UNDER THE FCA

Relators allege that Defendant engaged in off-label marketing activities which caused false claims to be filed, specifically certain promotional activities related to phantom limb pain. As detailed above, there are simply no specific factual allegations in this case that any claims for reimbursement were submitted to the Medicare program associated with the use of the Precision Plus™ SCS System for the treatment of phantom limb pain. This is a fatal and repetitive flaw in Relators' complaint, as Relators have once again failed to provide the who, what, where, when, and how as required under Rule 9(b). *Mason v. Coca-Cola Co.*, 774 F. Supp.2d 669, 702 (D.N.J. 2011). Moreover, Relators' claims must fail because they have failed to allege that Defendant engaged in any off-label marketing and that any such marketing could be actionable under the FCA.

A. By Relators' own description, there was no off-label promotion.

Relators' entire theory is premised on their belief that the treatment of phantom limb pain is an off-label use of the BSNC's SCS device. (Am. Compl. ¶ 94.) Whether the treatment of "phantom limb pain" is an off-label use of BSNC's device is a legal conclusion made by Relators and does not need to be accepted as true for purposes of a motion to dismiss. *See Iqbal*, 556 U.S. at 678 ("[T]he tenet

that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions.")

"The Precision Plus is approved by the FDA as an aid in the management of chronic intractable pain of the trunk and/or ***limbs***, including unilateral or bilateral pain associated with the following: failed back surgery syndrome, intractable low back pain and leg pain." (Am. Compl. ¶ 90) (emphasis added.) Relators make no effort to explain phantom limb pain falls outside the System's approved use, as by their own allegations Mike Roman has pain in his "phantom ***limb.***" (*Id. at.* ¶ 96) (emphasis added.) Instead, Relators only rely on a conclusory allegation that this is "an unapproved use." *See id.* At most, the question of whether the treatment of phantom limb pain is an "off-label" use is a regulatory "gray area" and violations of such unclear rules are not, as a matter of law, actionable under the FCA. *See, e.g., United States ex rel. Lamers v. City of Green Bay*, 168 F.3d 1013, 1018 (7th Cir. 1999) ("imprecise statements or differences in interpretation growing out of a disputed legal question are . . ..not false under the FCA"); *Wang v. FMC Corp.*, 975 F.2d 1412, 1421 (9th Cir. 1992) (court rejected relator's attempt to argue that defendant's method of resolving an engineering problem on a weapon system was actionable under the FCA because "false" does not mean "scientifically untrue," it means "a lie.")

Thus, Relators have not adequately pled that Defendants' "marketing" of their products for the treatment of phantom limb pain—even if it occurred as alleged by Relators—was "wrong." Moreover, there is no allegation in the complaint whatsoever that any Government Program patient received an implant to treat phantom leg pain. Such vague and conclusory pleadings should not be accepted by this Court and are not determinative as a matter of law.

B. Off-label promotion alone in the medical device context does not give rise a false claim.

Case law is clear, medical implants covered by the Medicare DMEPOS benefit may be reimbursable even when used off-label. "In the specific context of reimbursement claims for using a drug or device in a way that violates the FDA, the courts have held that the 'mere fact' of 'violating FDA regulations does not translate into liability for causing a false claim to be filed." *See United States ex rel. Bennett v. Boston Sci. Corp.*, No. H-07-2467, 2011 U.S. Dist. LEXIS 34745 at *45 (S.D. Tex. Mar. 31, 2011). The *Bennett* court described the differences between off-label use of a medical device and an unnecessary use, stating "Off-label use of many devices and drugs is an accepted medical practice. . . . Courts recognize that off-label use of a drug or medical device is not the same as a medically unnecessary use of that drug or device." *See id.* at *7-8. In fact, the court further noted that, "For medical devices eligibility for reimbursement

depends on whether the procedure performed is 'medically necessary' or 'reasonable and necessary.'" *See id.* at *16.

The Third Circuit has recently looked at off-label issues in a fraud context and similarly recognized that without more of a showing of fraud, off-label promotion in and of itself does not mean the prescription was medically unnecessary**.**

> Because the FDA does not regulate the practice of medicine, physicians may lawfully prescribe drugs for off-label uses. *See Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350, 121 S. Ct. 1012, 148 L. Ed. 2d 854 (2001) (recognizing off-label usage as "an accepted and necessary corollary of the FDA's mission to regulate in this area without directly interfering with the practice of medicine."); *Wash. Legal Found. v. Henney*, 202 F.3d 331, 333, 340 U.S. App. D.C. 108 (D.C. Cir. 2000) ("A physician may prescribe a legal drug to serve any purpose that he or she deems appropriate, regardless of whether the drug has been approved for that use by the FDA.") ."

In re Schering-Plough Corp. Intron/Temodar Consumer Class Action, 678 F.3d 235, 240 (3d Cir. 2012); *see also United States ex rel Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 308 (3d Cir. 2011) (finding that Medicare marketing activities could not give rise to liability under the False Claims Act.)

Here, Relators have failed to explain how Defendant submitted claims for external accessories that were medically unnecessary, because they were was used off label. The Relators have not pointed to a single physician that both received

off-label promotional materials from BSNC and then unnecessarily ordered a Precision Plus™ SCS System for a Medicare beneficiary. Without such an allegation, Relators have failed to provide the critical information that would establish the filing of a false claim or to satisfy Federal Rule of Civil Procedure 9(b). Consequently, Relators off-label allegation should be dismissed.

VIII. RELATORS HAVE NOT ALLEGED A KICKBACK SCHEME THAT WOULD GIVE RISE TO FALSE CLAIMS ACT LIABILITY.

Relators also claim, in a muddled way amidst their off-label promotion allegations, that BSNC improperly "provided physicians free reimbursement and prior authorization services to physicians to steer Government Program payments for on and off-label uses of the Precision Plus system." (Am. Compl. ¶ 98.) The Anti-Kickback Statute prohibits the solicitation or receipt of remuneration in return for referrals of patients covered by federal government programs and the payment of remuneration to induce such referrals. *See, e.g.*, 42 U.S.C. § 1320. The mere allegation of an Anti-Kickback Statute violation, however, is meaningless without evidence of subsequent claims made by providers as a result of the improprieties and evidence of receipt of federal funds in response to these claims that "was in some way conditioned on compliance with these regulations." *Wilkins*, 659 F.3d at 307; *See also United States ex rel. Karvelas v. Melrose-Wakefield Hosp.*, 360 F.3d 220, 232 (1st Cir 2004)) ("Underlying schemes and other wrongful activities that

result in the submission of fraudulent claims are included in the 'circumstances constituting fraud or mistake' that must be pled with particularity pursuant to Rule 9(b) . . . [and] such pleadings invariably are inadequate unless they are linked to allegations, stated with particularity, of the actual false claims submitted to the government that constitute the essential element of an FCA qui tam action").

Relators offer meager support for their claims of kickbacks by saying that these "reimbursements and prior authorization services" are of a "type that physicians would otherwise provide and pay for themselves." (Am. Compl. ¶ 98). However, that is the only detail Relators are able to provide about these purportedly illegal services. Rather than providing any detail about what specific services were offered, who the services were offered to, where the services were provided and when the services took place, Relators discuss generally U.S. Department of Health and Human Services Office of Inspector General ("OIG") guidance on reimbursement support services. (*See id.* at ¶102.) However, Relators fail to provide even the bare minimum of details that would be needed to determine if the OIG opinion cited is applicable to the case at bar.

Relators' complete failure to identify any reliable indicia of a kickback scheme including the failure to plead any false certifications made by physicians resulting in kickbacks, renders Relators' kickback allegations utterly defective.

While Relators allege that BSNC is bound by the certification in its supplier agreement, Relators have not alleged any details of an actual underlying scheme that would be non-compliant with respect to the Anti-Kickback statute.

IX. RELATORS HAVE NOT ALLEGED VIABLE RETALIATION CLAIMS

Not every employment termination is actionable under the False Claims Act. In order to demonstrate a viable § 3730(h) claim, a Relator

> must show (1) he engaged in protected conduct, (i.e., acts done in furtherance of an action under § 3730) and (2) that he was discriminated against because of [their] protected conduct. For a plaintiff to demonstrate that he was discriminated against because of conduct in furtherance of a False Claims Act suit, a plaintiff must show that (1) his employer had knowledge he was engaged in protected conduct; and (2) that his employer's retaliation was motivated, at least in part, by the employee's engaging in 'protected conduct.'

See United States ex rel. Hefner v. Hackensack Univ. Med. Ctr., 495 F.3d 103, 111 (3d Cir. 2007) (internal citations omitted).

A. Relators' alleged billing complaints do not qualify as "protected activity."

Despite Relators' claims of retaliation, the Relators' allegations in this case do not involve any protected activity. Relators allege generally that they complained to their supervisors about BSNC's billing practices. However, mere disagreements regarding billing practices are not enough to rise to the level of protected activity.

> In addressing what activities constitute protected conduct, the case law indicates that 'protected [conduct]' requires a nexus with the in furtherance of prong of [a False Claims Act] action. This inquiry involves determining whether [plaintiff's] actions sufficiently furthered 'an action filed or to be filed under' the [False Claims Act] and, thus, equate to 'protected [conduct].'

Hutchins v. Wilentz, 253 F.3d 176, 187 (3d Cir. 2001); *see also Dookeran v. Mercy Hosp. of Pittsburgh*, 281 F.3d 105, 108 (3d Cir. 2002) (following this reasoning). The Relators' allegations that they repeatedly made internal complaints about billing practices are not the same as putting BSNC on notice that their inquiries and complaints were in furtherance of an action to be filed under the FCA. Instead, as set forth above. The only thing BSNC was on notice of was Relators' lack of understanding around Medicare billing rules.

B. Relator Fuentes provides no allegations that she ever put BSNC on notice of her "protected activity."

Notably, Relator Bahnsen is the only Relator who even attempted, albeit insufficiently, to provide any detail about her internal complaints. (*See* Am. Compl. ¶¶ 148, 149, 154, 155, 156) (alleging facts related solely to Relator Bahnsen). Relator Fuentes should not be allowed to ride on the coattails of Relator Bahnsen, where Relator Fuentes shows by her silence that she has no facts to plead. Where there is "no way" of Relator Fuentes' complaints could "reasonably lead to a viable FCA action, then the whistle-blower provision provides [her] no protection." *See Dookeran,* 281 F.3d at 108. "Mere dissatisfaction with one's

treatment on the job is not, of course, enough. Nor is an employee's investigation of nothing more than his employer's non-compliance with federal or state regulations." *Hutchins*, 253 F.3d at 187-188 (3d Cir. N.J. 2001); *see also Zahodnick v. Int'l Bus. Mach. Corp.*, 135 F.3d 911, 914 (4th Cir. 1997) ("Simply reporting his concern of a mischarging to the government to his supervisor does not suffice to establish that *Zahodnick* was acting 'in furtherance of' a *qui tam* action.").

It is impossible to tell what, if any, activity Relator Fuentes is relying on to demonstrate that she engaged in any protected activity under the FCA. Given the complete lack of detail to these related claims, Relator Fuentes' retaliation claims must be dismissed.

C. Relator Bahnsen relies upon unsupported conjecture to allege protected activity.

Relator Bahnsen alleges that she made a series of internal complaints wasn't billing procedures. Then she adds the following sentence: "[f]ollowing the internal complaints to her employer, BSNC "*was informed"* that Relator Bahnsen intended to file a whistleblower case against BSNC." (Am. Compl. ¶ 161.) (emphasis added.) Relator Bahnsen provides no factual details around this allegation. She alleges only in passive voice that BSNC "*was informed*." (*See id.*) (emphasis added.) Relator does not allege that ***she*** put Defendant on any notice of protected

activity. The source of this information is unmentioned. Moreover, Relator does not identify who at BSNC was put on notice that she "intended to file a whistleblower case" or whether anyone at BSNC in a position to terminate Relator Bahnsen even knew of her intentions at all. Such vague and conclusory allegations cannot satisfy basic pleading requirements showing a plausible entitlement of relief. Consequently, Relator Bahnsen's retaliation claim must be dismissed.

X. RELATORS' STATE LAW CLAIMS SHOULD BE DISMISSED

Because Relators have failed to state any claim under the federal FCA, Defendants respectfully request that the Court decline to exercise jurisdiction over Relators' state law claims and dismiss the First Amended Complaint in its entirety. *See United States ex rel. Piacentile v. Sanofi Synthelabo, Inc.*, No. 05-2927, 2010 U.S. Dist. LEXIS 137895, at *27-28 (D.N.J. Dec. 30, 2010) (declining to exercise pendent jurisdiction over relator's state claims where relator's federal FCA claim failed to survive a motion to dismiss). State law claims filed in federal court are held to the same 9(b) standards, and for the reasons stated above, Relators' state law claims will suffer the same 9(b) fatality as the Medicare claims, and consequently should be dismissed. "We see no principled reason why . . . state claims of fraud should escape the pleading requirements of the federal rules." *Williams v. WMX Techs, Inc.*, 112 F.3d 175, 177 (5th Cir. 1997). Moreover,

Relators have failed to provide the factual basis for their claims under any state false claims act. As such, Relators' state claims should be similarly dismissed.

XI. CONCLUSION

For the foregoing reasons, Defendant respectfully requests that this Motion to Dismiss be granted.

Dated: October 24, 2012.

By: */s/ Felice B. Galant*

Felice B. Galant
Fulbright & Jaworski L.L.P.
666 Fifth Avenue
New York, New York 10103
Telephone: 212-318-3000
Telecopier: 212-318-3400
fgalant@fulbright.com

Frederick Robinson
(admitted *pro hac vice*)
Lesley C. Reynolds
(admitted *pro hac vice*)
Fulbright & Jaworski L.L.P.
801 Pennsylvania Avenue, NW
Washington, DC 20004
Telephone: 202-662-0200
Telecopier: 202-662-4643
frobinson@fulbright.com
lreynolds@fulbright.com

Attorneys for Defendant